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10/009,090	11/15/2001	Gordhanbhai Patel	PATL3.0-010	6317

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EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/009,090

Applicant(s)

PATEL, GORDHANBHAI

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9,13,15-40,42,44,46,48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9,13,15-40,42,44,46,48 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on July 18, 2005. Claims 1-6, 9, 13, 15-40, 42, 44, 46, 48-49 are pending.

#### Withdrawal of rejections from Previous Office Action

- The rejection under 35 USC 112, first paragraph is withdrawn in view of Applicants' incorporation of a substrate into the claims.
- The rejection under 35 USC 112, second paragraph is withdrawn in view of Applicants' amendments to better clarify the claims

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 9, 13, 16, 21-23, 27, 28, 30, 32-36, 42, 44, 46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,053,339 to Patel.

Patel teaches a device comprising a substrate (4) having an indicator composition and an activator composition disposed on the substrate. The substrate (1) is a flexible plastic film, as recited in claim 32 (col. 8, lines 9-10). The indicator composition is comprised of an indicator (3) dispersed in a polymeric matrix (9) and an activator (6) dispersed in a polymeric matrix (10). The indicator is taught as being a dye such as m-cresol purple or phenol red, as recited in claims 2-4 (col. 12, lines 33-63). The

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matrix into which the indicator is dispersed is taught as being a pressure sensitive polymer such as acrylates and acrylic acids and vinyl acetate (col. 10, lines 4-36). The activator is taught as being an amino compound, such as sodium thiocyanate, as recited in claims 21-23 (col. 35, example 14). The reference also teaches oxidants as the activator, allowing the indicator to undergo oxidation, as recited in claim 5 (col. 33, example 11). The polymeric matrix for the sodium thiocyanate activator in example 14 is vinyl acetate. Patel teaches that the matrices for both the indicator and activator may be the same (col. 7, lines 31-32), providing one polymeric matrix having an indicator and activator dispersed therein, as recited in claims 1 and 42. With respect to claim 6, Patel teaches dyes that change from red to blue and from yellow to blue in tables 2 and 3, shown at columns 15 and 16. With respect to claims 27 and 28, figure 3(c) of Patel shows a device having two layers, wherein the top layer is a polymeric layer. With respect to the methods of claims 30 and 48, Patel teaches that the device may be prepared by mixing the indicator (and activator) with the polymeric matrix and coating the matrix onto the substrate.

It is noted that Patel does not teach that the devices are for "monitoring plasma". However, this is considered to be Applicants' intended use, which is insufficient to patentably distinguish the instant claims over Patel. See MPEP 2111.02.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Patel.

3. Claims 1-6, 9, 13, 15-22, 27, 28, 34-36, 42, 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,005,572 to Raemer et al.

Raemer et al teach a detector device (38) comprising an indicator (68), phase transport enhancer and polymeric support. The indicator is a pH sensitive dye, such as phenol red and cresol purple, as recited in claims 3 and 4 (table 3). The phase transport enhancer is a bromide of a quaternary

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amine, equivalent to Applicants' claimed activator. Tetrabutylammonium hydroxide, as recited in claims 16-20, is taught at table 4 of Raemer et al. The polymeric support is a material, such as polyacrylamides and polyacrylates, as recited in claims 1, 13 and 42 (col. 8, lines 28-34). At col. 8, lines 28-29, Raemer et al teach that the indicator is adsorbed into the polymeric support material. With respect to claims 27 and 28, figure 4 of Raemer et al teach a device having multiple layers and having a polymeric layer on top.

It is noted that Raemer et al do not teach that the devices are for "monitoring plasma". However, this is considered to be Applicants' intended use, which is insufficient to patentably distinguish the instant claims over Patel. See MPEP 2111.02.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Raemer et al.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claims 1-9, 15-21, 24, 27, 28, 30-35, 37-44, 48 and 49 rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al in view of US patent 6,395,551 to Kipke et al.

Ignacio et al disclose a composition and device for monitoring sterilization processes.

The composition comprises a dye (indicator) and a halogen source (activator) within a binder resin (polymer), as recited in claims 1 and 42 (col. 3, lines 8-9). The dye is one that is susceptible to halogenation, as recited in claim 5. Phenol red, a pH indicator, is disclosed as an example, as recited in claims 3 and 4 (col. 3, lines 10-19). With respect to claim 6, Ignacio et al disclose an example of a sterilization monitoring composition where phenol red is used as the indicator. After exposure to peracetic acid, the composition turned from red to yellow (col. 10, line 66 – col. 11, line 15). With respect to the activator, Ignacio discloses halogen sources including as alkali metal halides such as potassium bromide, as recited in claims 16-19 (col. 3, lines 31-39). The reference also discloses using quaternary amines, such as tetra alkyl ammonium bromides, as recited in claims 19 - 21 (col. 6, lines 57-60). With respect to claim 24, Ignacio et al disclose using a microporous bottom (40) that helps control the amount of vapor that contacts the indicator composition (col. 10, lines 18-19). With respect to claims 27 and 28, figure 1 of the reference shows a multi-layered device wherein the top layer (30) is made of polymeric material (col. 10, lines 4-6). With respect to claims 30-35, where Applicants claim the process of making the device, Ignacio discloses dissolving the components of the composition in an alcohol solvent and applying the composition to blotter paper (col. 4, lines 38-62). The composition may be in the form of ink and the substrate may be in the form of a strip or label (col. 3, line 64 – col. 4, line 19). With respect to claims 40-41, where Applicants claim the use of the device in monitoring sterilization processes, Ignacio et al disclose that the device may be used to monitor peracetic acid or hydrogen peroxide sterilization

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processes (col. 5, lines 49-59). Ignacio et al further disclose that the sterilization indicators may be used to monitor sterilization processes that include a plasma step, as recited in claims 37 and 49.

Ignacio et al differ from the instant invention in that there is no disclosure of the particular polymers recited by Applicants.

Kipke et al teaches an indicator for sterilization solutions that provides a visual detector of exposure of the device to a sterilization solution. The device contains a pH indicator disposed within a polymer coating as the indicator. The polymer coating is one such as copolymers of vinyl acetate and polyacrylamide, such as claimed by Applicants (col. 3, lines 32-67). Kipke et al teach that in selecting a polymer such as these, the indicator is aided in reacting with the sterilization solution to provide an effective color change (col. 3, lines 21-30). Kipke et al further teach incorporating a crosslinking agent into the indicator system, as recited in claims 24 and 25 (col. 4, lines 64-66).

It would have been obvious to one of ordinary skill in the art to use vinyl acetate or polyacrylamide polymers in the sterilization indicators of Ignacio et al to aid the indicator in changing colors in response to sterilization. Further, it would have been obvious to incorporate crosslinking agents into the device of Ignacio et al to immobilize the indicator in the polymer.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 103 in view of the teachings of Ignacio et al in view of Kipke et al.

7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of US patent 5,045,283 to Patel.

The disclosure of Patel is described above. Patel differs from the instant invention in that it fails to teach a wedge-shaped polymeric layer.

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Patel '283 teaches that by making the top polymeric layer in the form of a wedge, a movable observable color change is provided. It would have been obvious to one of ordinary skill in the art to provide a wedge-shaped polymeric top layer in the device of Patel '339 so that the results of the color change can be seen throughout the length of the device.

### *Response to Arguments*

8. Applicant's arguments with respect to the pending claims have been considered but are not deemed to be persuasive.

With respect to the rejection over Patel, Applicants argue that the reference teaches that a barrier may be present in between the two layers of indicator and activator. Also, Applicants argue that the matrix for the indicator and activator may be different.

The Examiner does not disagree with Applicants' assessment of Patel's teachings. Applicants have, however, disregarded the portions of Patel, which teachings anticipate Applicants' claims directly. At col. 7, lines 52-64, Patel teaches that the device is activated by laminating the indicator tape to the activator tape. Previously, Patel stated that tapes are pressure sensitive adhesives. Thus, once the two layers are laminated, a composite layer film is formed. Patel specifically teaches that the matrix (10) used in making the indicator tape and activator tape may be the same or different. This option of the tapes having the same matrix material and being laminated together expressly anticipates Applicants' claim. The Examiner agrees that Patel teaches a separate option of the matrix materials being different – which teaching does not apply to Applicants' claims. However, one cannot disregard the teaching that the matrix materials can be the same, when such teaching anticipates Applicants' claims.

With respect to the Raemer reference, Applicants argue that the reference teaches a different use of the indicator tapes and that the indicator is "attached" to the support. In response, the Examiner notes



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that the prior art may teach a different use for an apparatus. Claims directed to an apparatus are distinguished by their structure, not their intended use. See MPEP 2111.02. With respect to the indicator being "attached" to the support, Raemer teaches that the indicator and activator are absorbed onto the polymeric support. The Examiner agrees that the Raemer reference also teaches covalent attachment, but one cannot disregard the teaching of the indicator and activator being absorbed onto the polymeric support. In fact, Raemer also teaches one of the properties of the support is its ability to absorb the indicator (col. 8, lines 37-38).

With respect to the obviousness rejection over Ignacio in view of Kipke, Applicants continue to argue whether the device of Ignacio may be used for plasma sterilization detection. The Examiner will continue to rely on Ignacio's specific teaching that plasma sterilization may be detected to support the rejection. Applicants' argue that the plasma sterilization is not possible using a paper substrate. However, the teachings of Ignacio are not limited to paper substrates, as polyester substrates and plastic substrates are taught as well.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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